Sections included in this Document and Document History

1. Purpose

To describe the procedure for the receipt, resolution, and maintenance of records of complaints regarding FDA, Office of Regulatory Affairs (ORA) laboratory activities. Complaints are objections, errors, or non-conformities involving work quality, or failures to provide service or other requests of the customer including timeliness. Complaints can provide valuable feedback on the effectiveness of the organization and can be used to improve the organization with the customer in mind.

2. Scope

This procedure is applicable to all FDA, ORA laboratory organizational units and personnel.

3. Responsibilities

Laboratory management is responsible for ensuring the implementation of the complaint procedure and facilitates process changes. Supervisors and staff are responsible for recording complaints received on the complaint form, initiating corrective action or forwarding to the local manager for corrective action. The Quality Management System (QMS) Manager monitors the comments and complaints received for trends, resolutions and corrective action.

4. Background

None

5. References

None

6. Procedure

A. Complaints may be lodged by various means in writing, electronically through e-mail, by telephone, and in person.

B. Complaints can result from:

- internal customers which include other laboratory branches and offices within the laboratory's district office;
- external customers which include Division of Field Science (DFS), other ORA districts, FDA Centers, other government agencies, regulated industry, private laboratories, or consumers; and
- staff.

C. Complaints may be categorized by their source and impact on work quality or service to customers. Complaint categories are as follows:

- Level I – complaints received from within the laboratory and involve only one branch;
- Level II – complaints received from within the laboratory and involve more than one branch;
- Level II – complaints received from within the home district if the laboratory is part of a district;
- Level IV – complaints received from other ORA laboratories, districts, DFS or Centers; and
- Level V – complaints received from outside FDA.

6.1 Receiving Complaints

A. Staff who receive a complaint documents it on the laboratory's Complaint Form (CF).

B. The CF includes:

- the affiliation of the person and organization who lodged the complaint,
- the date the complaint was received, and
- the nature of the complaint.

6.2 Processing Complaints

A. If the person receiving the complaint can determine the cause and the corrective action, they should take the corrective measures, complete the complaint form and forward it to the identified supervisor.

B. If the cause and corrective action can not be determined by the person receiving the complaint, submission of the complaint is made to laboratory

management.

C. Any complaint that cannot be resolved is referred to the next higher level of management.

D. A corrective action report is generated and the laboratory's corrective action process initiated. This process involves the determination and investigation of adverse impact on operations and quality.

6.3 Closing and Monitoring

A. When the corrective action has been completed, the complaint is closed. The CF and corrective action form is forwarded to the identified manager.

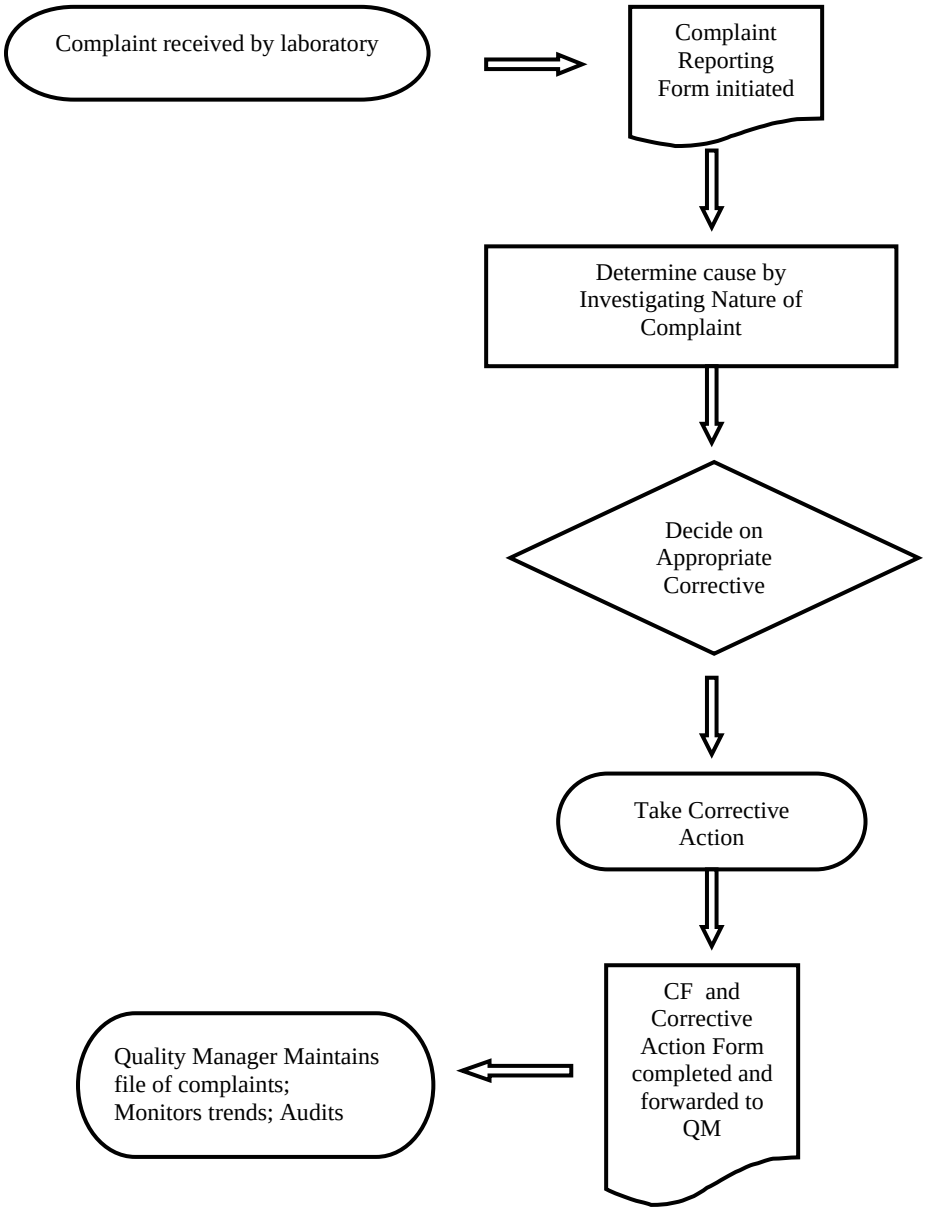
B. Both forms are submitted to the Quality Management System Manager who reviews the CF for completeness and files the forms.

C. Complaints are reviewed in the internal audit and management review to ensure any changes from a complaint were proper, effective, timely and successful.

6.4 Complaint Process Flowchart

A. The complaint process is illustrated in the flowchart.

Complaint Process Flowchart.



7. Definitions

Complaints – Complaints are negative comments about the organization's (i.e. district, laboratory) activities, work product or service received from internal or external customers.

Corrective action – This is the action taken to eliminate the causes of a detected non-conformance, defect or other undesirable situation in order to prevent reoccurrence.

8. Records

Complaint form
Corrective Action form

9. Supporting Documents

ORA Laboratory Manual, Volume II, Section 1, ORA-LAB.4.10 Corrective Action Procedure

10. Attachments

None

Document History

Version No.	Status (I, R, C)	Date Approved	Location of Change History	Name & Title	
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